Message

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Subject: FW: FYI only. Inside EPA on IRIS

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From: D'Amico, Louis <DAmico.Louis@epa.gov>
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Subject: FYI only. Inside EPA on IRIS

https://insideepa.com/tsca-news/former-top-epa-lawyer-sees-iris-rise-incoming-biden-administration

Former Top EPA Lawyer Sees IRIS' Rise With Incoming Biden Administration
December 16, 2020
Former Trump EPA General Counsel Matthew Leopold is expecting the incoming Biden Administration to resurrect the agency's Integrated Risk Information System (IRIS), once EPA's influential top risk analysis program but which has been marginalized in the Trump EPA in favor of the nascent new TSCA program.

"The incoming administration will likely reprioritize IRIS risk assessments over TSCA and keep [EPA's Office of Research and Development (ORD)] playing a pivotal role in conducting hazard assessments. The key questions will be whether the IRIS methodology will predominate over the TSCA program and what happens if the processes differ as to the same chemical substance, given TSCA's new, more muscular approach," Leopold, who served almost three years as the Trump EPA's general counsel before stepping down last September to join the law firm Hunton Andrews Kurth, wrote in a Dec. 16 blog post with colleague Gregory Wall.

Leopold and Wall, formerly a senior attorney at EPA and now counsel at Hunton Andrews Kurth, wrote their blog post on the subject of the new draft IRIS handbook the agency recently released for public comment and peer review.

But they raise questions about how the IRIS and TSCA programs will coexist in the Biden EPA and whether the IRIS program and its conservative hazard assessment approaches may gain primacy over EPA's toxics office and its approach to evaluating risks from select conditions of use under the revised Toxic Substances Control Act (TSCA).

The attorneys do not explain why they anticipate that a Biden EPA will prioritize IRIS assessments over TSCA evaluations.

But one explanation may be found in report language House Democrats last summer attached to EPA's fiscal year 2021 appropriations bill, which called on EPA to stop divesting IRIS' resources in favor of the TSCA program and appeared to direct that IRIS develop the initial steps of all EPA chemical assessments, including those being evaluated in the TSCA program.

Democrats in the report raised concerns that the Trump EPA is inappropriately shifting staff from IRIS to support EPA's Office of Pollution Prevention and Toxics (OPPT), charged with implementing Congress' 2016 reform of TSCA. "The Committee remains deeply concerned that the Agency has been ignoring Congressional directives and inappropriately assigning resources provided for [IRIS] to support work in [OPPT]," the July 9 report states.

The "Committee expects that workforce costs for IRIS staff who have been detailed to other programs or to other agencies will be borne by the hosting program or agency. Additionally, to ensure a neutral, systematic, and independent evaluation of the science underlying its decisions, the Agency is directed to utilize [ORD] to develop the hazard identification and dose-response portions of all Agency risk assessments. The Agency may realign [personnel] to the [ORD] as necessary."

It is unclear from the report language if the Committee is directing ORD to develop hazard identification and dose-response values for OPPT. For the first 10 evaluations of existing chemicals that OPPT has developed to date under the reformed TSCA, the office has relied in part on existing IRIS assessments where they exis -- a fact which has led to criticism from some industry groups, who have long opposed the IRIS program for its often-conservative approach to assessing chemicals' human health risks.

New IRIS Assessments

Another question, according to Leopold and Wall, will be whether ORD or EPA program offices are responsible for initiating new IRIS assessments. "The draft handbook notes that the development of IRIS assessments requires consultation and close coordination with EPA programs, which could suggest that EPA programs may have more input in directing IRIS assessments in the future," they write.

While program office requests for risk analyses assistance from IRIS have long driven that program's agenda, Administrator Andrew Wheeler further tightened the program offices' hold on IRIS' agenda during his tenure, calling for a months-long review of the assessments on IRIS' agenda and developing a new, annual review system for setting its agenda based on requests from program offices' political leadership.

This approach led EPA to halve the number of chemicals on IRIS' agenda and to move its particularly controversial formaldehyde assessment, long underway within IRIS, to the TSCA program instead.

Wheeler's approach to the program led to criticism from the Government Accountability Office, which charged that the administrator had delayed and minimized with program without good cause.

And environmentalists and Democrats have strongly criticized shifting the formaldehyde evaluation from IRIS to TSCA and continue to call for EPA to release the latest IRIS draft.

Leopold and Wall argue that the shift was appropriate. "TSCA risk evaluations go beyond general toxicity assessments performed under IRIS and determine whether the chemical presents an unreasonable risk to health or the environment under the chemical's 'conditions of use.'"

Such findings under TSCA trigger risk management regulation to address the unreasonable risks.

But IRIS' proponents, such as its former chief Tina Bahadori, have argued that the program is still necessary because IRIS has a broader mandate to conduct risk analyses for all agency program offices -- with the Superfund office in particular needing such assistance because it lacks inhouse capacity to do so. Some have also argued that the narrow evaluations the TSCA program has so far produced will not be as useful to other program offices.

Bahadori left EPA last summer for the National Academy of Sciences (NAS) after EPA's reorganization of ORD shifted her away from IRIS to lead a smaller research program.

IRIS analyses are not risk assessments per se. Instead, the assessments contain hazard identification and dose-response analyses, resulting in risk estimates that can be adapted by agency program offices for different exposure pathways and environmental media as needed in their own risk management efforts.

But because IRIS focuses on hazard, rather than risk, its analyses often result in conservative values that drive strict regulatory requirements. As such, they draw stiff opposition from industry groups and other regulatory entities who have been urging EPA to abandon use of IRIS values in regulatory decisions.

TSCA Evaluations

Leopold and Wall suggest that Biden administration "efforts to bolster the IRIS process could also directly impact evaluations under the TSCA program . . . Ultimately, the IRIS Handbook may influence potential changes to the TSCA program as well," noting that an NAS committee is currently reviewing the systematic review approach OPPT developed for the TSCA program and has been using to conduct its first 30 evaluations.

The approach has come under criticism from environmentalists and some systematic review experts, who argue that its use in the first 10 evaluations resulted in the TSCA evaluations downgrading or dismissing studies indicating important risks.

NAS committee members also appear to have raised some concerns with the TSCA systematic review approach, leading to an announcement that officials are considering dropping a controversial scoring system for evaluating study quality.

EPA announced with its release of the draft IRIS handbook, which had been underway for nearly a decade, since NAS' critical evaluation of EPA's draft 2010 evaluation of formaldehyde led to ongoing efforts to increase the program's rigor and transparency in large part by implementing systematic review, that it would also seek NAS peer review of its systematic review approach. Congress' 2016 reform of TSCA and its new requirements that EPA's toxics office conduct risk evaluations of existing chemicals, once largely the province of IRIS, slowed agency efforts to reform the program.

The attorneys' blog post steps through the IRIS handbook's approach for developing IRIS assessments, largely focused on its approach to conducting systematic reviews, a stepwise approach to gathering and evaluating scientific literature. The handbook also contains a first-time system for classifying chemicals' non-cancer risks, based on the labeling approach IRIS and other programs have long used to classify chemicals' carcinogenic potential. Both issues reportedly delayed release of the draft document because of concerns from agency toxics officials.

Comments are due on the IRIS handbook by March 1. NAS has yet to announce when or how it will conduct the peer review. -- Maria Hegstad (mhegstad@iwpnews.com)

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